Bayer

Pharmaceutical
Division

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September 13, 1999

Dockets Management Branch (HFD-305)
Food and Drug Administration
5630 Fishers Lane
Room 1061
Rockville, MD 20852

Re: Docket # 98D-0077
Draft Guidance for Industry: Clinical Development Programs for Drugs, Devices and Biological Products Intended for the Treatment of Osteoarthritis (OA). Federal Register 135, July 15, 1999.

Dear Sir/Madam

Bayer Corporation, Pharmaceutical Division appreciates the opportunity to comment on this revised draft Guidance. As a member of PhRMA, we agree and support the letter signed by Dr. Michael J. Horan and submitted to the docket #98D-0077 on September 13, 1999. In addition we have the following complementary comment as noted in the paragraph below.

1. Section V.B.3 Slow JSN by at least a pre-specified amount/ <u>Effect size of >50% is too high a hurdle given current state of OA science</u>: The last sentence of this paragraph in the draft Guidelines requires the sponsors to anticipate >50% change in slowing of JSN relative to control arm. We agree with the members of the FDA Arthritis Advisory Committee on July 21, 1999 that this drug effect is unreasonably high, and suggest that a drug effect of approximately 30% be accepted as an initial guide. Additionally, during the same Advisory Committee discussions, the issue of specifying a minimum absolute value for joint space width (JSW) change was brought up. We would like to mention that since the absolute change in JSW depends on the JSW at the beginning of the study, asking for a minimal absolute effect will not be practical and can result in either a very large study, or exclusion of patients with low JSW at baseline. A percentage effect on progression of JSN is sufficient to show efficacy of compounds that have a structure modification effect.

Sincerely,

Gautam Shah, Ph.D.
Associate Director
Regulatory Affairs

98D-0077

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